Union Calendar No. 250

108TH CONGRESS
2D SESSION

S. 1881

[Report No. 108–433]

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2003

Referred to the Committee on Energy and Commerce

MARCH 9, 2004

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of Senate passed bill, see copy of bill as referred in the House of Representatives on December 8, 2003]

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to make technical corrections relating to the amendments made by the Medical Device User Fee and Modernization Act of 2002, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medical Devices Technical Corrections Act".

SEC. 2. TECHNICAL CORRECTIONS REGARDING PUBLIC LAW 107–250.

(a) TITLE I; FEES RELATING TO MEDICAL DEVICES.—Part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as added by section 102 of Public Law 107–250 (116 Stat. 1589), is amended—

(1) in section 737—

(A) in paragraph (4)(B), by striking "and for which clinical data are generally necessary to provide a reasonable assurance of safety and effectiveness" and inserting "and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness";

(B) in paragraph (4)(D), by striking "manufacturing,";

(C) in paragraph (5)(J), by striking "a premarket application" and all that follows and inserting "a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act."; and

(D) in paragraph (8), by striking "The term 'affiliate' means a business entity that has a relationship with a second business entity" and inserting "The term 'affiliate' means a busi-

ness entity that has a relationship with a second business entity (whether domestic or international)"; and

(2) in section 738—

(A) in subsection (a)(1)—

(i) in subparagraph (A)—

(I) in the matter preceding clause (i) by striking "subsection (d)," and inserting "subsections (d) and (e),";

(II) in clause (iv), by striking "clause (i)," and all that follows and inserting "clause (i)."; and

(III) in clause (vii), by striking "clause (i)," and all that follows and inserting "clause (i), subject to any adjustment under subsection (e)(2)(C)(ii)."; and

(ii) in subparagraph (D), in each of clauses (i) and (ii), by striking "application" and inserting "application, report,";

(B) in subsection (d)(2)(B), beginning in the second sentence, by striking "firms. which show" and inserting "firms, which show";

(C) in subsection (e)—

(i) in paragraph (1), by striking "Where" and inserting "For fiscal year 2004 and each subsequent fiscal year, where"; and

(ii) in paragraph (2)—

(I) in subparagraph (B), beginning in the second sentence, by striking "firms. which show" and inserting "firms, which show"; and

(II) in subparagraph (C)(i), by striking "Where" and inserting "For fiscal year 2004 and each subsequent fiscal year, where";

(D) in subsection (f), by striking "for filing"; and

(E) in subsection (h)(2)(B)—

(i) in clause (ii), by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively;

(ii) by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively;

(iii) by striking "The Secretary" and inserting the following:

"(i) IN GENERAL.—The Secretary"; and

(iv) by adding at the end the following:

"(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.".

(b) TITLE II; AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES.—

(1) INSPECTIONS BY ACCREDITED PERSONS.—Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)), as added by section 201 of Public Law 107–250 (116 Stat. 1602), is amended—

(A) in paragraph (1), in the first sentence, by striking "conducting inspections" and all that follows and inserting "conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i).";

(B) in paragraph (5)(B), in the first sentence, by striking "or poses" and all that follows through the period and inserting "poses a threat

to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.";

(C) in paragraph (6)(A)—

(i) in clause (i), by striking "of the establishment pursuant to subsection (h) or (i) of section 510" and inserting "described in paragraph (1)";

(ii) in clause (ii)—

(I) in the matter preceding subclause (I)—

(aa) by striking "each inspection" and inserting "inspections"; and

(bb) by inserting "during a 2-year period" after "person"; and

(II) in subclause (I), by striking "such a person" and inserting "an accredited person";

(iii) in clause (iii)—

(I) in the matter preceding subclause (I), by striking "and the following additional conditions are met:" and inserting "and 1 or both of the following additional conditions are met:";

(II) in subclause (I), by striking "accredited" and all that follows through the period and inserting "(accredited under paragraph (2) and identified under clause (ii)(II)) as a person authorized to conduct such inspections of device establishments."; and

(III) in subclause (II), by inserting "or by a person accredited under paragraph (2)" after "by the Secretary";

(iv) in clause (iv)(I)—

(I) in the first sentence—

(aa) by striking "the two immediately preceding inspections of the establishment" and inserting "inspections of the establishment during the previous 4 years"; and

(bb) by inserting "section" after "pursuant to";

(II) in the third sentence—

(aa) by striking "the petition states a commercial reason for the waiver;"; and

(bb) by inserting "not" after "the Secretary has not determined that the public health would"; and

(III) in the fourth sentence, by striking "granted until" and inserting "granted or deemed to be granted until"; and

(v) in clause (iv)(II)—

(I) by inserting "of a device establishment required to register" after "to be conducted"; and

(II) by inserting "section" after "pursuant to";

(D) in paragraph (6)(B)(iii)—

(i) in the first sentence, by striking ", and data otherwise describing whether the establishment has consistently been in compliance with sections 501 and 502 and other" and inserting "and with other"; and

(ii) in the second sentence—

(I) by striking "inspections" and inserting "inspectional findings"; and

(II) by inserting "relevant" after "together with all other";

(E) in paragraph (6)(B)(iv)—

(i) by inserting "(I)" after "(iv)"; and

(ii) by adding at the end the following:

"(II) If, during the two-year period following clearance under subparagraph (A), the Secretary determines that the device establishment is substantially not in compliance with this Act, the Secretary may, after notice and a written response, notify the establishment that the eligibility of the establishment for the inspections by accredited persons has been suspended.";

(F) in paragraph (6)(C)(ii), by striking "in accordance with section 510(h), or has not during such period been inspected pursuant to section 510(i), as applicable";

(G) in paragraph (10)(B)(iii), by striking "a reporting" and inserting "a report"; and

(H) in paragraph (12)—

(i) by striking subparagraph (A) and inserting the following:

"(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);"; and

(ii) in subparagraph (E), by striking "obtained by the Secretary" and all that follows and inserting "obtained by the Secretary pursuant to inspections conducted by Federal employees;".

(2) OTHER CORRECTIONS.—

(A) PROHIBITED ACTS.—Section 301(gg) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(gg)), as amended by section 201(d) of Public Law 107–250 (116 Stat. 1609), is amended to read as follows:

"(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.".

(B) ELECTRONIC LABELING.—Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), as amended by section

206 of Public Law 107–250 (116 Stat. 1613), is amended, in the last sentence—

(i) by inserting "or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments" after "in health care facilities";

(ii) by inserting a comma after "means";

(iii) by striking "requirements of law and, that" and inserting "requirements of law, and that";

(iv) by striking "the manufacturer affords health care facilities the opportunity" and inserting "the manufacturer affords such users the opportunity"; and

(v) by striking "the health care facility".

(c) TITLE III; ADDITIONAL AMENDMENTS.—

(1) EFFECTIVE DATE.—Section 301(b) of Public Law 107–250 (116 Stat. 1616), is amended by striking "18 months" and inserting "36 months".

(2) PREMARKET NOTIFICATION.—Section 510(o) of the Federal Food, Drug, and Cosmetic Act (21

U.S.C. 360(o)), as added by section 302(b) of Public Law 107–250 (116 Stat. 1616), is amended—

(A) in paragraph (1)(B), by striking ", adulterated" and inserting "or adulterated"; and

(B) in paragraph (2)—

(i) in subparagraph (B), by striking ", adulterated" and inserting "or adulterated"; and

(ii) in subparagraph (E), by striking "semicritical" and inserting "semi-critical".

(d) MISCELLANEOUS CORRECTIONS.—

(1) CERTAIN AMENDMENTS TO SECTION 515.—

(A) IN GENERAL.—

(i) TECHNICAL CORRECTION.—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)), as amended by sections 209 and 302(c)(2)(A) of Public Law 107–250 (116 Stat. 1613, 1618), is amended by redesignating paragraph (3) (as added by section 209 of such Public Law) as paragraph (4).

(ii) MODULAR REVIEW.—Section 515(c)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(B)) is amended by striking "unless an issue of

safety'' and inserting ''unless a significant issue of safety''.

(B) CONFORMING AMENDMENT.—Section 210 of Public Law 107–250 (116 Stat. 1614) is amended by striking '', as amended'' and all that follows through ''by adding'' and inserting ''is amended in paragraph (3), as redesignated by section 302(c)(2)(A) of this Act, by adding''.

(2) CERTAIN AMENDMENTS TO SECTION 738.—

(A) IN GENERAL.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)), as amended by subsection (a), is amended—

(i) in the matter preceding paragraph (1)—

(I) by striking ''(a) Types of Fees.—Beginning on'' and inserting the following:

''(a) TYPES OF FEES.—

''(1) IN GENERAL.—Beginning on''; and

(II) by striking ''this section as follows:'' and inserting ''this section.''; and

(ii) by striking "(1) PREMARKET APPLICATION," and inserting the following: "(2) PREMARKET APPLICATION,".

(B) CONFORMING AMENDMENTS.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by subparagraph (A), is amended—

(i) in subsection (d)(1), in the last sentence, by striking "subsection (a)(1)(A)" and inserting "subsection (a)(2)(A)";

(ii) in subsection (e)(1), by striking "subsection (a)(1)(A)(vii)" and inserting "subsection (a)(2)(A)(vii)";

(iii) in subsection (e)(2)(C)—

(I) in each of clauses (i) and (ii), by striking "subsection (a)(1)(A)(vii)" and inserting "subsection (a)(2)(A)(vii)"; and

(II) in clause (ii), by striking "subsection (a)(1)(A)(i)" and inserting "subsection (a)(2)(A)(i)"; and

(iv) in subsection (j), by striking "subsection (a)(1)(D)," and inserting "subsection (a)(2)(D),".

(C) ADDITIONAL CONFORMING AMENDMENT.—Section 102(b)(1) of Public Law 107–250 (116 Stat. 1600) is amended, in the matter preceding subparagraph (A), by striking "section 738(a)(1)(A)(ii)" and inserting "section 738(a)(2)(A)(ii)".

(3) PUBLIC LAW 107–250.—Public Law 107–250 is amended—

(A) in section 102(a) (116 Stat. 1589), by striking "(21 U.S.C. 379F et seq.)" and inserting "(21 U.S.C. 379f et seq.)";

(B) in section 102(b) (116 Stat. 1600)—

(i) by striking paragraph (2);

(ii) in paragraph (1), by redesignating subparagraphs (A) and (B) as paragraphs (1) and (2), respectively; and

(iii) by striking:

"(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—

"(1) IN GENERAL.—A person submitting a premarket report"and inserting:

"(b) FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS.—A person submitting a premarket report"; and

(C) in section 212(b)(2) (116 Stat. 1614), by striking ", such as phase IV trials,".

SEC. 3. REPORT ON BARRIERS TO AVAILABILITY OF DEVICES INTENDED FOR CHILDREN.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children. The report shall include any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices.

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